

Food and Drug Administration, HHS

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once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

(ii) *Indications for use.* For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations.* Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, Mar. 5, 2010]

§ 520.666 Dirlotapide.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007]

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) [Reserved]

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

(c) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5
Hookworms (<i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	
Strongyloides (<i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i>)	10	10–12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013]

§ 520.763b Dithiazanine iodide powder.

(a) [Reserved]

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5

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	Milligrams per pound of body weight	Length of treatment— days
Hookworms (<i>Ancylostoma</i> <i>caninum</i> , <i>Uncinaria</i> <i>stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	7
Strongyloides (<i>Strongyloides</i> <i>canis</i> , <i>stercoralis</i>)	10	10–12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams of piperazine base (as piperazine citrate).

(b) *Sponsor.* See 054628 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; $\frac{3}{4}$ ounce for each 100 pounds thereafter, up to 1,200 pounds; $10\frac{1}{4}$ ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum*; small strongyles; large strongyles, *Strongylus vulgaris*; and pinworms, *Oxyuris equi*.

(3) *Limitations.* Administer by drench or mixed with the daily ration as a sin-

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gle dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013]

§ 520.766 Domperidone.

(a) *Specifications.* Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) *Sponsor.* See No. 043264 in §510.600 of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) *Indications for use.* For prevention of fescue toxicosis in periparturient mares.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 67031, Nov. 1, 2010]

§ 520.784 Doxylamine succinate tablets.

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

(b) *Sponsor.* See No. 000061 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.